K113630

philosys, Inc.

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MAR 8 2013

510(k) SUMMARY

(As required by 21.CFR.807.92)

Introduction: According to the requirements of 21 CFR.807.92, the following information provides sufficient data to understand the basis for a determination of substantial equivalence.

Submitted By:
Philosys Co Ltd
304 Park Avenue South
Suite 218
New York, NY 10010

Contact Person:
Linda Chan
Phone: 917-757-3793
Fax: 800-931-9137

Date Summary Prepared: December 8, 2011

Device Name:
Propriety Name: Gmate® VOICE Blood Glucose Monitoring System and Ch
Common Name: Blood Glucose Test System
Classification Name: Class II, 862.1345 Blood Glucose Monitoring System
Product Code: CGA – Glucose Oxidase, Glucose
NBW – System, Test, Blood Glucose, Over the Counter

Propriety Name: Gmate® Control Solution
Classification Name: Class I, 21 CFR 862.1660, Quality Control Material (assayed and unassayed)
Product Code: JJX – Single Analyte Controls (assayed and unassayed)

Predicate Device: We claim substantial equivalence to the OneTouch® ULTRA® System Manufactured by LifeScan, Inc., K002134.

Device Description: The Gmate® VOICE Blood Glucose Monitoring System is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood, which is used with the Gmate® Blood Glucose Test Strips.

The test principle is:

This device is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the glucose oxidase that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

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510(k) SUMMARY

(As required by 21.CFR.807.92)

Intended Use:

The Gmate® VOICE Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, hand, upper arm, forearm, calf or thigh as an aid in monitoring the effectiveness of diabetes management in the home by individuals with diabetes. The Gmate® VOICE Blood Glucose Monitoring

System is intended to be used by a single user and should not be shared with any other person.

Gmate® VOICE Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Gmate® VOICE Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Gmate® VOICE Blood Glucose Monitoring System includes a speaking feature that provides audible test results for diabetic users.

The Gmate® Blood Glucose Test Strips are for use with the Gmate® VOICE Meter for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, hand, upper arm, forearm, calf or thigh.

The Gmate® Control Solution is for use with the Gmate® VOICE Blood Glucose Monitoring System and is intended as a quality control measure to verify the accuracy of your blood glucose test results and to ensure that the Gmate® VOICE meter and Gmate® Test Strips are working properly. The Gmate® Control Solution is intended for use by people with diabetes at home.

Comparison to Predicate Device:

The Gmate® VOICE Blood Glucose Monitoring System is substantially equivalent to the other products in commercial distribution intended for similar use. The most notable, it is substantially equivalent to the currently marketed item, OneTouch® ULTRA® System Manufactured by LifeScan, Inc., K002134.

Conclusion:

The Gmate® VOICE Blood Glucose Monitoring System is substantially equivalent to the following predicate device:
OneTouch® ULTRA® System Manufactured by LifeScan, Inc., K002134.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Philosys, Inc.
C/O Linda Chan
304 Park Avenue South, Suite 218
New York, NY 10010

Re: k113636
Trade/Device Name: Gmate VOICE™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, NBW, JJX
Dated: February 14, 2013
Received: February 15, 2013

Dear Ms. Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113636

Device Name: Gmate® VOICE Blood Glucose Monitoring System

Indications for Use:

The Gmate® VOICE Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, hand, upper arm, forearm, calf or thigh as an aid in monitoring the effectiveness of diabetes management in the home by individuals with diabetes. The Gmate® VOICE Blood Glucose Monitoring System is intended to be used by a single user and should not be shared with any other person.

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Prescription Use_____	AND/OR	Over-The-Counter Use__X___
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostic and Radiological Health

510(k) k113636